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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,569	10/05/2005	Anne Galy	268501US0XPCT	5033

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EXAMINER

WOLLENBERGER, LOUIS V

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/528,569

Applicant(s)

GALY ET AL.

Examiner

Louis V. Wollenberger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the application/amendments

Applicants' amendment to the claims, filed 10/5/05, is acknowledged. With the amendment, claims 1-11 are pending and subject to restriction as follow.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, drawn to a method for obtaining isolated or cultured antigen presenting cells, wherein the expression of one or more target genes is down-regulated, comprising introducing siRNA(s) directed against said target genes, and to methods thereof wherein the siRNA(s) may be directed to a gene encoding the p50 subunit of NF-kappaB, TNF-receptor associated factor 3, or the c-Rel subunit of NF-kappaB. Election of this group requires the further election of a single siRNA target gene from claim 3, as explained below.

Group II, claim(s) 4-6 and 11, drawn to an siRNA directed against a gene encoding the p50 subunit of NF-kappaB, and to expression vectors and compositions thereof.

Group III, claim(s) 4-6 and 11, drawn to an siRNA directed against a gene encoding the TNF-receptor associated factor 3, and to expression vectors and compositions thereof.

Group IV, claim(s) 4-6 and 11, drawn to an siRNA directed against a gene encoding the c-Rel subunit of NF-kappaB, and to expression vectors and compositions thereof.

Group V, claim(s) 7, 8, and 10 drawn to an antigen-presenting cell obtainable by the method of claim 1, and to a composition comprising activated T lymphocytes obtainable by the method of claim 1.

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Group VI, claim(s) 9, drawn to a method for producing T lymphocytes that fail to produce IFN-gamma, comprising inducing activation of naïve T cells by co-cultivating said T cells with antigen presenting cells of claim 7, containing siRNA directed against a gene encoding p50.

The inventions listed as Groups I–VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I–VI is an siRNA directed against a target gene in an antigen presenting cell, such as any siRNA directed against the genes encoding the p50 subunit of NF-kappaB, the TNF-receptor associated factor 3, or the c-Rel subunit of NF-kappaB. However, this cannot be the special technical feature, because the element(s) is/are shown in or obvious in view of the prior art. For example, Narayanan et al. (US Patent 5591840) teach antisense oligonucleotides against the gene encoding the p50 subunit of NF-kappaB (see Fig. 2; Example 1, col. 8; and column 3, lines 55-60, for example). Narayanan et al. teach that the genes encoding the p50 and p65 subunits of NF-kappaB have been cloned (col. 1, lines 25-40). Narayanan et al. teach and suggest inhibiting p50 expression to prevent cell adhesion in therapeutic applications using antisense oligonucleotides. In view of Tuschl et al. (US Patent Application Publication 2004/0259247 A1), who teach and suggest the use of siRNA against any known gene, and that siRNA is at least an order of magnitude more potent than antisense oligos (paragraph 148), there is a presumption that siRNAs directed to the gene encoding the p50 subunit is/are obvious. Accordingly, unity of invention is lacking, *a posteriori*, among Groups I–VI.

Unity of invention is lacking *a priori* among Groups II, III, and IV, since the groups lack the same or corresponding special technical feature. The special technical features of the groups are, in turn, siRNA(s) directed against a gene encoding the p50 subunit of NF-kappaB, TNF-receptor associated factor 3, or the c-Rel subunit of NF-kappaB.

Accordingly, unity of invention is lacking.

In addition, should applicants elect to prosecute Group I, this group is subject to further restriction as follows.

Group I contains a claim, claim 3, that recites a plurality of different methods requiring the use of at least three distinct siRNAs directed against three different genes: p50, TNF-receptor associated factor 3, or the c-Rel subunit of NF-kappaB.

The siRNAs directed to the target genes, and therefore the methods using these siRNAs, would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity.

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In the instant case, the description fails to disclose that all three of the target genes share a common property or activity. Moreover, there is no disclosure teaching that the target genes are homologous to each other. Therefore, they fail to share a common structure i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since it is shared by all nucleic acid molecules. Therefore, the target genes do not share any significant structural element and cannot be considered as having the same or corresponding technical feature. Consequently, the group of target genes claimed does not meet the requirement of unity of invention (a priori) (See MPEP 803.02 and Annex B(f) of the PCT Administrative Instructions). Logically, since each of the target genes comprises a distinct sequence, different siRNAs and therefore different methods would be required to down regulate each gene.

Accordingly, Applicants are required to elect one target gene for prosecution with Group I.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

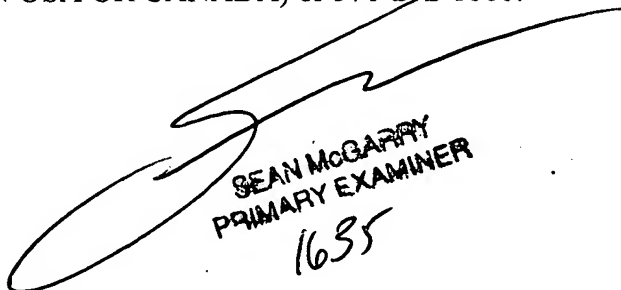
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571)272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Louis Wollenberger
Examiner, Art Unit 1635
September 27, 2006


SEAN MCGARRY
PRIMARY EXAMINER
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